国家药品监督管理局
National Medical Products Administration

# The latest progress of Medical Device Regulation in China

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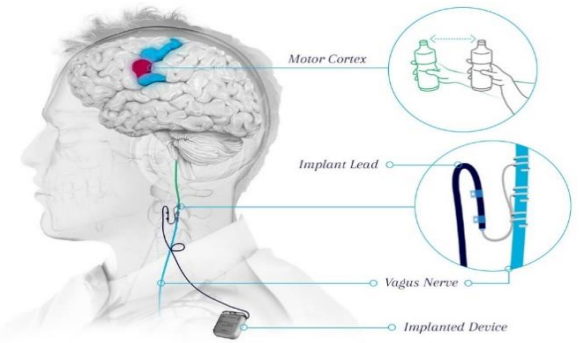

PART 1

PART 1

# Work Progress of Medical Device Regulation in 2025


# Continuously encourage the innovative development of the medical device industry.

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**Announcement of the National Medical Products Administration on Issuing the Initiatives for Optimizing Whole Life Cycle Regulation to Support the Innovation and Development of High-end Medical Devices (No.63, 2025)**

01 Optimize Special Review and Approval Procedures

02 Improve Classification and Nomenclature Principles

03 Continuously Improve the Standard System

04 Further Clarify the Registration Review Requirements

05 Improve the Communication Guidance Mechanism and Expert Consultation Mechanism

06 Refine Post-marketing Regulatory Requirements

07 Strengthen Post-marketing Quality and Safety Monitoring

08 Closely Follow up on Industry Development

09 Promote Regulatory Science Research

10 Promote Global Regulatory Harmonization

- Medical Robots
- AI MD
- high-end medical imaging equipment,
- new biomaterials MD

# 1 Continuously Improve the Regulatory Law and Regulation System

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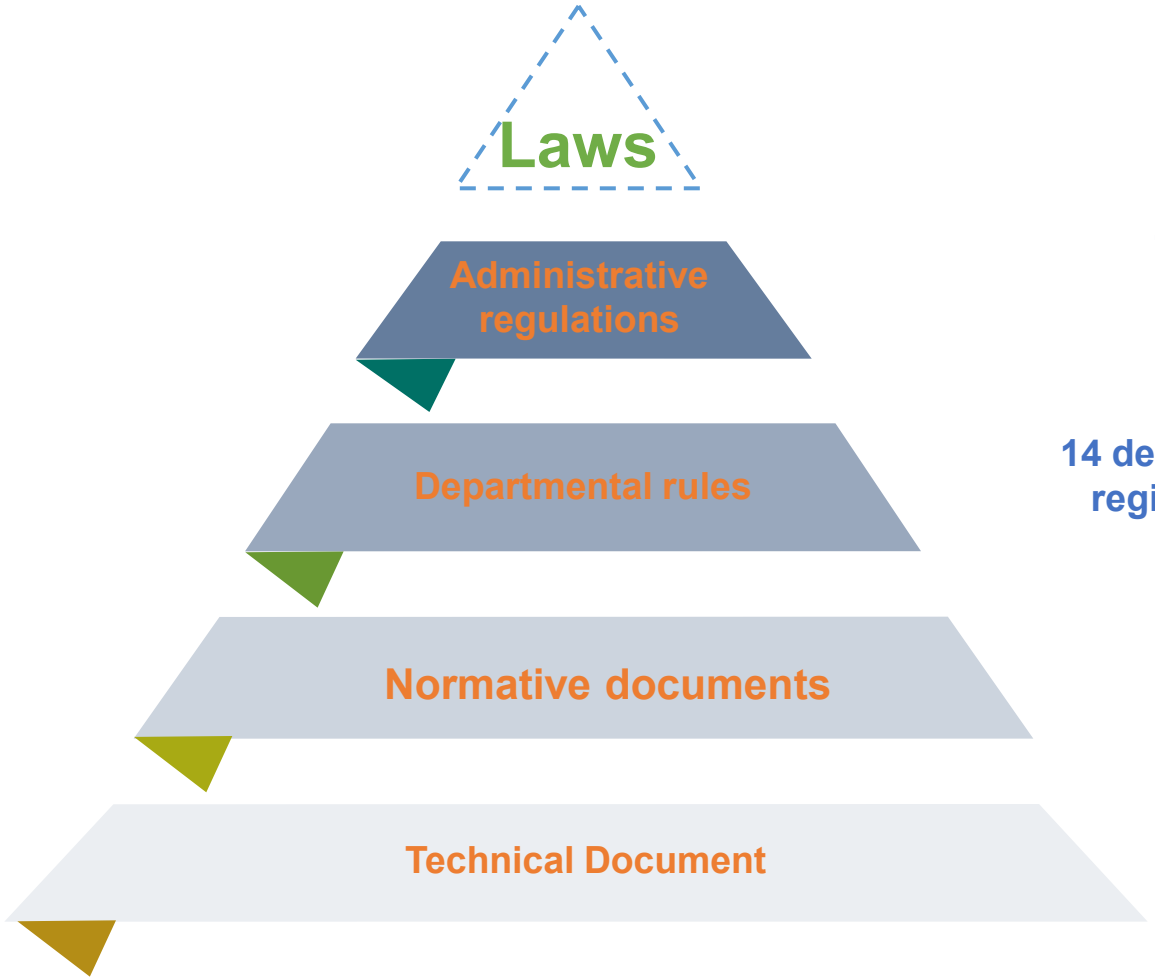



## Medical Device Administration Law (Draft)

The Regulations for the Supervision and Administration of Medical Devices (Decree No. 739 of the State Council of the People's Republic of China) was implemented on June 1, 2021.

14 departmental rules covering the whole life cycle regulation, including product registration, production, operation, use, adverse event monitoring, and recall

140+ normative documents
seven new regulatory documents was release

2,080 medical device standards, over 647 technical guidelines related to registration, production, and operation

# Issued 7 important regulatory documents in 2025

1. The Classification Catalogue of In-Vitro Diagnostic Reagents;

2. The Announcement on Further Adjust and Optimize Relative Matters for Imported Medical Devices Manufactured in Enterprises within the Territories of China (2025 No.30);

3. The Announcement on Issuing the Key Points and Processing Principles of Inspections for Clinical Trials of Medical Devices;

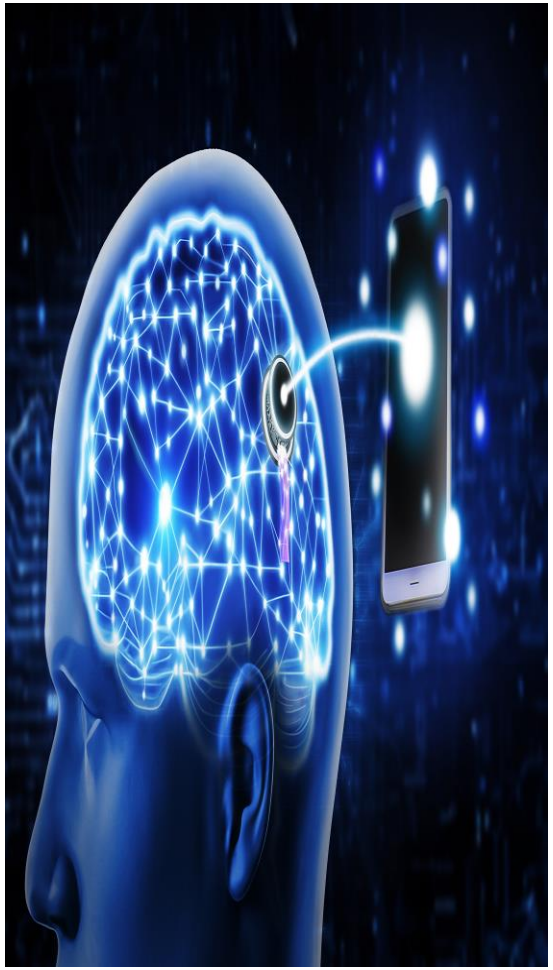
4. 2025 Directory of Medical Devices Exempted from Clinical Evaluation;

5. 2025 Directory of In-Vitro Diagnostic Reagents Exempted from Clinical Trials;

6. Good Supply Practices of Online Sales for Medical Devices;

7. Good Manufacturing Practice for Medical Devices （On November 4, 2025）

# Technical standard for brain computer interface medical devices were released for industry



1.Medical Devices Utilizing Brain-Computer Interface - Glossary(an industry recommended standard for medical devices issued by the NMPA on September 15, 2025)

It is China's first standard for brain-computer interface (BCI) medical devices, which lays the foundation for high-quality industry development of the BCI medical devices. This standard systematically establishes a glossary of terms for BCI medical devices, clarifying core terms and their definitions such as basic concepts, paradigm types, signal forms, signal processing and applications etc.

2.Brain-computer interface medical device—Closed-loop implantable neurostimulator—Test method for sensing and response performance issued by the NMPA on September 26, 2025)

This document describes a test method for the neural signal sensing and response performance of implantable neurostimulators that adopt brain-computer interface using closed-loop functionality.

# 2 Expedite the marketing of innovative medical devices

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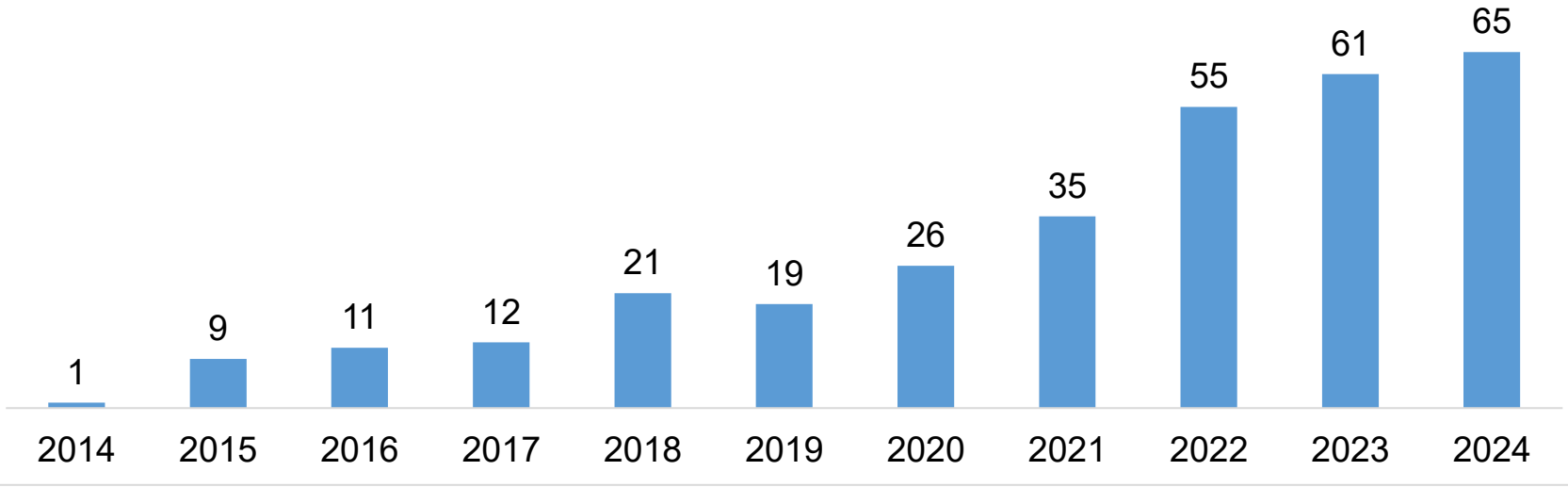
## Number of Approved Innovative Medical Devices from 2014 to 2024




As of 2025, 66 innovative medical devices have been approved.

As of November 21, 2025 NMPA has approved a total of 381 innovative medical devices for marketing and conducted priority review and approval for 160 medical devices.

The number of innovative products has been increasing year by year.

Implantable left ventricular assist system

Vascular prosthesis

Proton therapy system

Endoscopic surgical robot

# 3 Further strengthen the management of clinical trials

**01**

Institutes where clinical trials are conducted are no longer subject to the review and approval system but the filing system. As of early July, 1,677 clinical trial institutions of medical devices had been filed, greatly relieving the pressure of fewer clinical trial institutions of medical devices.

**02**

Good Clinical Practice for Medical Devices (GCP) and emphasize the process standardization of clinical trials to ensure the authenticity, accuracy, integration, and traceability of clinical trial results

**03**

The Measures for the Supervision and Inspection of Clinical Trial Institutions of Medical Devices (Trial) was implemented on October 1, 2024, guiding inspection authorities at all levels to strengthen the management of clinical trial institutions of medical devices.

**04**

Announcement on Issuing the Key Points and Determination Principles for the Inspection of Medical Device Clinical Trials
March 12, 2025
Refine the key points and content of inspection, improve the principles for determining the inspection results, and clarify the requirements for handling the inspection results

# 4 Continuously improve the classification management

**A** — Issue the *Opinions on Further Strengthening and Improving the Classification Management of Medical Devices to strengthen the top-level design*

**B** — The *Rules for the Classification of Medical Devices* is under revision

**C** — Dynamically adjust the *Classification Catalogue of Medical Devices*

**D** — Issued the *Rules for the Classification of In Vitro Diagnostic Reagents*

**E** — Revised and issued the *Classification Catalogue for In Vitro Diagnostic Reagents*

# 5 Promote the application of UDI in marketed medical device products

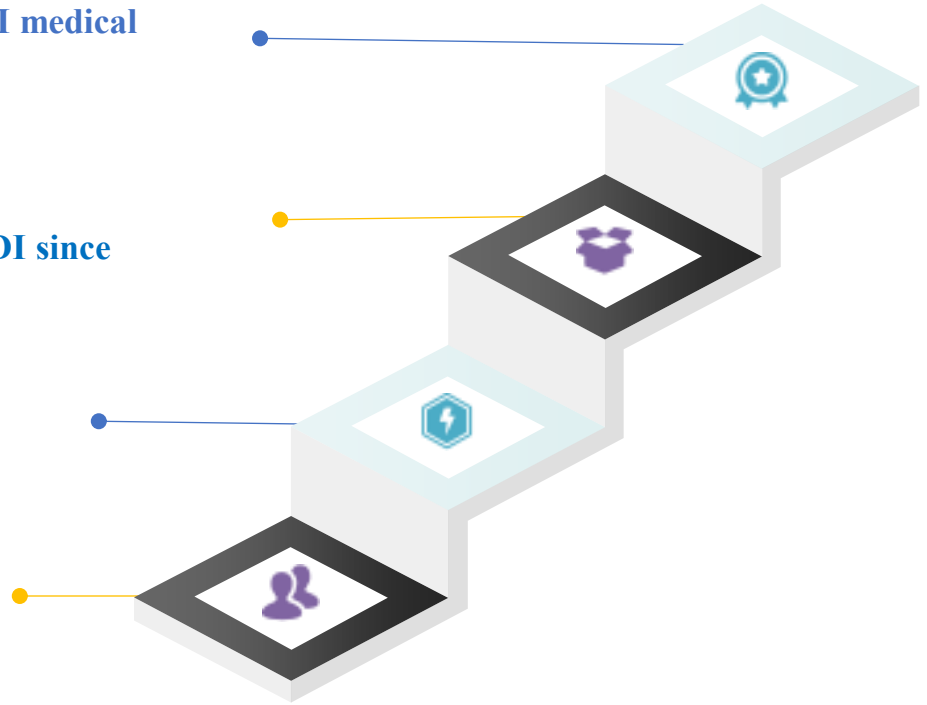
UDI

2025 NMPA has organized the drafting of the Announcement on Implementing Unique Device Identification for Medical Devices in Specific Situation。It is proposed to implement UDI for all Class II medical devices (including in vitro diagnostic reagents) and all Class I in vitro diagnostic reagents since June 1, 2027, and for all Class I medical devices since June 1, 2029.

2024 The 103 kinds of Class II medical devices has officially implemented UDI since June 1, 2024.

2022 The remaining Class III medical devices (including in vitro diagnostic reagents) are included in the second batch and has officially implemented UDI since June 1, 2022.

- 2021 The first batch of 69 medical devices in 9 major categories (all of which are Class III devices with high risks) has officially implemented UDI



**Establish a complete management system**

**Promote the implementation in batches**

# 6 Deeply promote scientific research on medical device regulation

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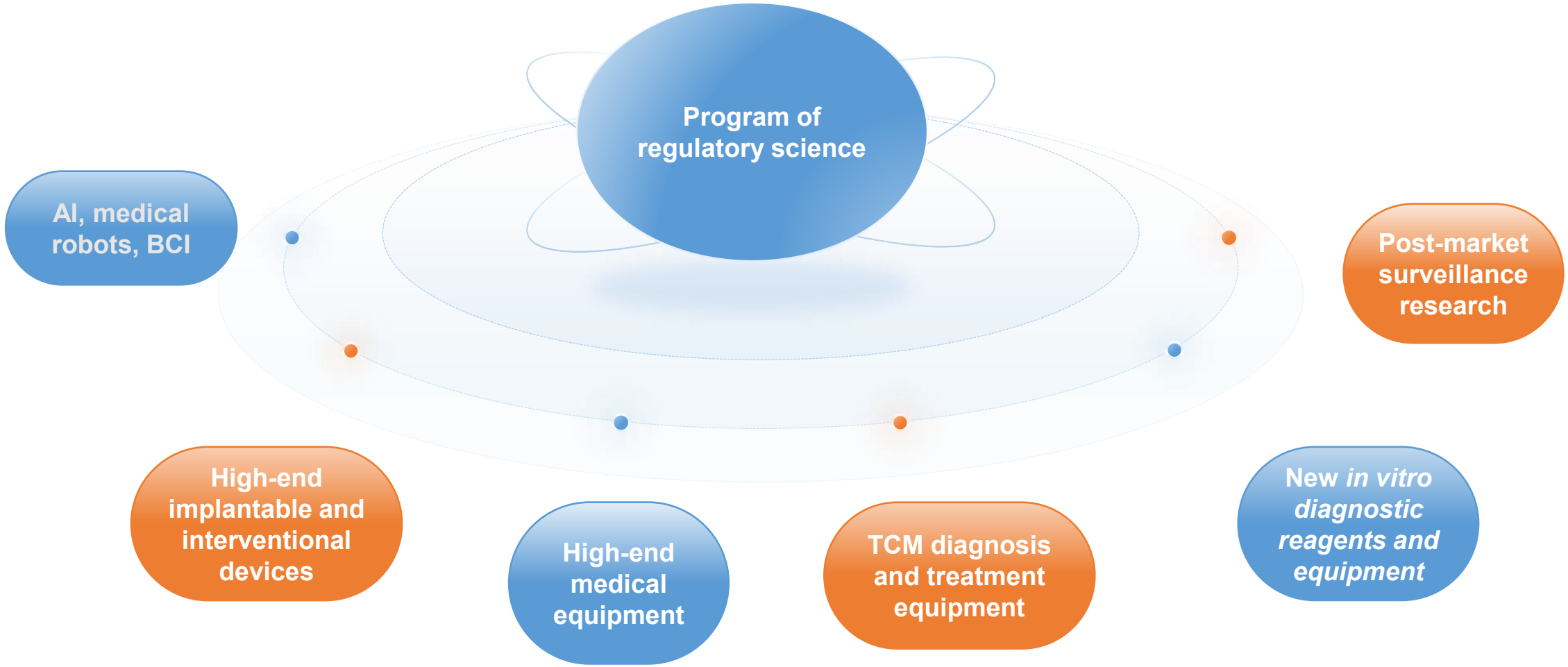

PART 1

PART 2

# International communication & coorperation in 2025

# 1 To Adopt GHWP Guidance Documents Actively

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| | |
|---|---|
| six<br>Fully Adopted | 1.Regulatory Mechanism for Medical Devices Including In Vitro Diagnostic Medical Devices and Software as Medical Devices During A Public Health Emergency<br>2.Guidance Document for Medical Device Organizations-Product Localisation for Manufacturing and Importation<br>3.Guidance for Audit Supplier to Medical Device Manufacturers<br>4.Guidance Document on the Risk-Based Approach to Quality Management System Aspects: ISO13485:2016<br>5. UDI Rules<br>6.Creation and Placement of Unique Device Identifier |
| four<br>Partially Adopted | 1.Change Management to Registered Medical Devices<br>2.Categorisation of Changes to a Registered Medical Device<br>3.Guidance for Additional Considerations to support Conformity Assessment of In vitro Companion Diagnostic Medical Device<br>4.Medical Gas System- Essential Principals of Safety and Performance |
| one<br>Not Implemented | Principles of Regulatory Requirements for Electronic Instructions for Use (eIFU) |

# 2 Support the Construction of GHWP (China) Academy

Global Harmonization Working Party
GHWP Towards Medical Device Harmonization

To accelerate the enhancement of regulatory capabilities in member countries and regions, GHWP has established physical training institutes. After careful preparation, South China University of Technology in China has been approved as the world's first GHWP medical device training college - GHWP (Guangzhou) College - in 2023 with its outstanding innovation and transformation capabilities. In 2025, the college successfully held two large-scale training sessions and completed a total of four training sessions.

On November 18, 2025, GHWP officially announced that GHWP (Guangzhou) College would be renamed GHWP (China) College, marking a new stage of development for GHWP (China) College ,based in China and serving the world.


# 3 Support the CMEF in hosting the GHWP Innovative Medical Device Symposium

Global Harmonization Working Party
Towards Medical Device Harmonization

GHWP signed a strategic cooperation agreement with China National Pharmaceutical Group Exhibition Co., Ltd.（CMEF）on November 22, 2023. To date, GHWP and CMEF have successfully organized two Innovation Medical Device Reports, featuring invited speeches by representatives of multiple innovative product entrepreneurs.

In 2024 and 2025, GHWP has already established dedicated booths at the China Medical Device Spring Expo for two consecutive years.


# 4 Expand Opening-up and Promote International Exchange and Cooperation

World Health Organization

IMDRF International Medical Device Regulators Forum

NMPA has actively designated relevant personnel to attend the working meetings held by counterpart international organizations on the formulation and revision of relevant standards. A total of 432 experts have registered with the International Organization for Standardization (ISO).

Actively participate in the work of IMDRF

NMPA has taken the lead in issuing 4

IMDRF guidelines for clinical evaluation.

NMPA has established contacts with drug regulatory authorities in more than 60 countries or regions and signed more than 30 cooperation documents with 30 of them.

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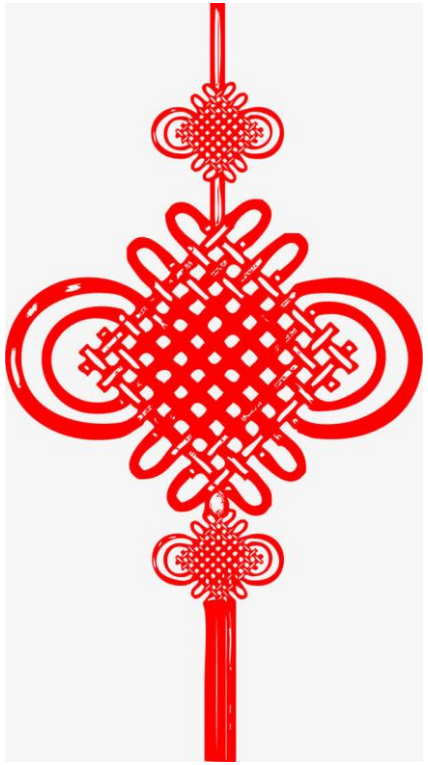
# Safeguard the public health as our beloved ones!



# THANK YOU